JAN 2 5 2001

K003385

510(k) Summary of Safety and Effectiveness Information

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

Company: BioLase Technology, Inc.
981 Calle Amanecer
San Clemente, CA 92673

Contact: Ms. Ioana M. Rizoiu
BioLase Technology, Inc.
981 Calle Amanecer
San Clemente, CA 92673
(949) 361-1200 (949) 361-0204 Fax

Trade Name: *Twilite™, TwiliteWhite™*

Common Name: Dental diode laser

Classification Name: Surgical laser instrument

Classification Code:79 GEX

Equivalent Devices:

Premier Laser Systems	*Arago™*
LaserMed	*AccuCure 1000 & 3000™*
ICS of North America	*Cyber-Lase 2000™*
HGM Medical	*Dental 200, 300 & 400*

Device Description:

The *Twilite™* dental diode laser system may be used to perform several dental applications. *Twilite™* uses advanced laser technology to incise, excise and ablate intraoral soft tissues and to activate a bleaching material for whitening/bleaching teeth safely and effectively. A Gallium Aluminum Arsenide (GaAlAs) solid state laser diode provides optical energy to oral soft tissues and tooth bleaching compounds.

A flexible fiberoptic handpiece delivers the *Twilite™* laser energy. A visible light emitted from the handpiece distal end pinpoints the area of treatment. The optical power output and pulse may be adjusted to specific user requirements.

Indications for Use:

Light activation for bleaching materials for teeth whitening.

Laser-assisted Bleaching/Whitening of the teeth.

Cautions and Contraindications:

All clinical procedures performed with ***Twilite***™ must be subjected to the same clinical judgement and care as with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient's medical history prior to treatment. Exercise caution for general medical conditions that might contraindicate a local procedure. Such conditions may include allergy to local or topical anesthetics, heart disease, lung disease, bleeding disorders, sleep apnea or an immune system deficiency. Medical clearance from patient's physician is advisable when doubt exists regarding treatment.

Substantial Equivalence:

There are no unique applications, indications, materials or specifications presented herein. ***Twilite***™ is identical to several other laser systems cleared by the FDA. Equivalent devices include: Premier, *Arago* (K971118), LaserMed, *AccuCure 3000*™ (K943411) and *AccuCure 1000*™ (K970637) for light activation for bleaching materials for teeth whitening and ICS of North America, *Cyber-Lase 2000*™ (K983654) and HGM, *Dental 200, 300 and 400* (K991464) for assisting in the whitening process and laser-assisted bleaching / whitening of teeth.

Conclusion:

Twilite™ is substantially equivalent to several available, established dental laser products. ***Twilite***™ performs through the same mechanism as other laser technologies.

- Evidence of equivalence has been demonstrated through:
- Equivalent performance specifications
- Promotional materials for equivalent systems
- Equivalent intended uses

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Ioana Rizoiu
Vice President, Clinical Research
and Development
Biolase Technology, Inc.
981 Calle Amanecer
San Clemente, California 92673

Re: K003385
Trade Name: TwiLite™, TwiLite White™
Regulatory Class: II
Product Code: GEX
Dated: October 27, 2000
Received: October 31, 2000

Dear Ms. Rizoiu:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, ~~Ph.D.~~, ~~M.D.~~
Director
Division of ~~General, Restorative~~
and Neurological Devices
Office of ~~Device Evaluation~~
Center for Devices and
Radiological ~~Health~~

Enclosure

510(k) Number (if known): K003385

Device Name: *TwiLite™, TwiLite White™*

Indications for Use:

Light activation for bleaching materials for teeth whitening.

Laser-assisted whitening/bleaching of teeth.

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003385

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter-Use _____
(Per 21 CFR 801.109)